REMARKS

The Official Action dated January 16, 2008 and references cited therein have been carefully reviewed. In view of the amendments and Terminal Disclaimer submitted herewith, and the following remarks. favorable reconsideration and allowance of this application are respectfully requested.

Status of the prosecution.

This amendment is in response to a final Office Action following Applicant's filing of a response and Request for Continued Examination, a supplemental response following an examiner interview, a response to a non-final rejection, and a second examiner interview.

Claims 163-182 were finally rejected in the January 16, 2008 Office Action. Claim 176 was rejected under 35 U.S.C. §112, first paragraph, on the ground that the recitation in claim 176 of an adhesive polymer matrix that comprises "more than 10% and less than about 30% by weight" of the combination of skin permeation enhancing agents has introduced new matter. Claims 163-182 remain rejected on the ground of nonstatutory double patenting as allegedly unpatentable over claims 1-34 of U.S. Patent 7,045,145. Claims 163-166 and 171-182 remain rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. 5,762,956 (the 956 patent) in view of U.S. 5,023,084 (the 084 patent). Claims 167-170 remain rejected under 35 U.S.C. §103(a) as allegedly unpatentable over the 956 patent in view of the 084 patent, and in view of U.S. 6,007,835 (the 835 patent).

Interview summary.

A telephonic interview between the examiner and Applicant's undersigned attorney was conducted on February 19, 2008. Applicant's attorney thanks the examiner for her time and courtesy in granting the interview and considering proposed claim amendments to advance the application to allowance. The claim amendments discussed in the February 19, 2008 interview are essentially the same as those submitted in this paper, with one exception.

In the proposed claim amendment, element (c) of claim 163 recited: "a combination of skin permeation enhancing agents comprising, on a final percentage by weight of the adhesive polymer matrix after fabrication of the system, from about 4% to about 12% dimethyl sulfoxide; from about 4.2% to about 12.6% a fatty (C_8-C_{20}) alcohol ester of lactic acid; from about 0.7% to about 2.3% lower (C_1-C_4) alkyl ester of lactic acid; and from about 3% to about 9% capric acid." The examiner stated that the claims should be held allowable if the term "comprising" in element (c) of claim 163 was changed to "consisting essentially of," and if Applicant's after-final response included a Terminal Disclaimer to overcome the obviousness-type double patenting rejection.

Current amendments to the specification and/or claims.

Accordingly, to advance the claims to allowance, claim 163 has been amended to recite a transdermal hormone delivery system that includes a combination of skin permeation enhancing agents consisting essentially of, on a final percentage by weight of the adhesive polymer matrix after fabrication of the system, from about 4% to about 12% dimethyl sulfoxide; from about 4.2% to about 12.6% a fatty (C_8-C_{20}) alcohol ester of lactic acid; from about 0.7% to about 2.3% lower (C_1-C_4) alkyl ester of lactic acid; and from about 3% to about 9% capric acid. Claim 176 was amended to recite a system comprising between about 12% and about 36% by weight skin permeation enhancers in the final formulation. Pending dependent claims 181 and 182 have not been amended; they continue to recite more specific limitations to the amount of capric acid in the adhesive polymer matrix. New dependent claims 183-188 recite more specific limitations to the amounts of the other three skin permeation enhancers in the adhesive polymer matrix. Support for these claim amendments and new claims may be found throughout the specification, *e.g.*, at paragraph 0066, among others. Further, the present application teaches how to make the claimed transdermal hormone delivery system throughout the specification; *e.g.*, at paragraphs 0062-0064 and in Example 3.

Applicant submits that presently pending claims are in condition for allowance, for the reasons set forth below.

The alleged new matter has been deleted from claim 176.

Claim 176 was rejected under 35 U.S.C. §112, first paragraph, on the ground that the recitation in claim 176 of an adhesive polymer matrix that comprises "more than 10% and less than about 30% by weight" of the combination of skin permeation enhancing agents has introduced new matter. Claim 176 has been amended to recite that the adhesive polymer matrix comprises about 12% to about 36% by weight of the combination of skin permeation enhancing agents. Support for current claim 176 is found at paragraph 0065 of the specification and therefore does not constitute new matter. Reconsideration and withdrawal of the rejection is requested.

A Terminal Disclaimer is submitted herewith to overcome the nonstatutory obviousness-type double patenting rejection.

Claims 163-182 remain rejected on the ground of nonstatutory double patenting as allegedly unpatentable over claims 1-34 of commonly-owned U.S. Patent 7,045,145. A terminal disclaimer in compliance with 37 CFR 1.321(c) or (d) is submitted herewith. Reconsideration and withdrawal of the rejection is therefore requested.

The claimed subject matter is not obvious in view of the cited prior art.

Claims 163-166 and 171-182 remain rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. 5,762,956 (the 956 patent) in view of U.S. 5,023,084 (the 084 patent). Claims 167-170 remain rejected under 35 U.S.C. §103(a) as allegedly unpatentable over the 956 patent in view of the 084 patent, and in view of U.S. 6,007,835 (the 835 patent).

Applicant submits that the subject matter of claims 163-166, 171-182 and new claims 183-188 is patentable over the 956 patent in view of the 084 patent. As pointed out previously, the 956 patent teaches away from adding anything to the three-enhancer combination disclosed therein. Through its repeated use of the term "consisting of," and

"unique combination," the 956 patent teaches that its three enhancer system is not amenable to alteration or supplementation.

In contrast, the transdermal delivery system of the present invention specifies a combination of four skin permeation enhancers, clearly taught against by the 956 patent, wherein the enhancers are present in specific amounts that are nowhere suggested by the 956 patent, and indeed are not mandated against by the weight ratios of enhancers taught by the 956 patent. The 084 patent does not supply the requisite teachings that are absent from the 956 patent, and indeed teaches away from the use of capric acid in the low amount currently specified in the amended claims,[1] particularly as combined with the specific ranges of the other enhancers recited in the claims.

Hence, there is no rational basis taken from either the 084 or the 956 patent, or the combination of those teachings, to impart to the skilled artisan any reason for modifying the amounts of enhancers in the manner currently claimed, or for adding 3-9% by weight of capric acid to produce the presently claimed transdermal delivery system. Accordingly, the claimed system cannot be said to be obvious in view of the teachings of those two patents.

Applicant further submits that the subject matter of claims 167-170 is patentable over the 956 patent taken with the 084 patent and the 835 patent. The addition of the 835 patent to support the rejection of claims 167-170 is untenable in view of the absence of teaching in the 956 patent and the 084 patent of the invention as currently claimed. The 835 patent's purported teaching of PVP/VA-S30 does not supply a reason to combine the teachings of the cited references so notably absent from the primary references.

For the foregoing reasons, the claimed subject matter is nonobvious over the cited references. Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) is therefore requested.

---

[1] As the Office has acknowledged, the 084 patent teaches capric acid as a skin permeation enhancer for certain progestins and estrogens, in an amount as low as 10%, with preferred ranges being 15-30% (w/w) (col. 17, lines 53-57). However, there is nothing in the 084 patent to suggest to the skilled artisan that addition of *less than* 10% of capric acid would be a useful modification to the 956 patent's system. And indeed, by specifying a range of 10-40% and a preferred range of 15-30%, addition of less than 10% of capric acid is taught away from by the 084 patent.

Conclusion.

In view of the amendments and Terminal Disclaimer submitted herewith and the foregoing remarks, the presently pending claims are believed to be in condition for allowance. Applicant respectfully requests early and favorable reconsideration and withdrawal of the rejections set forth in the January 16, 2008 Official Action, and allowance of this application.

Respectfully submitted,

Date: February 22, 2008

Janet E. Reed, Ph.D.
Registration No. 36,252

Drinker Biddle & Reath, LLP
One Logan Square
18th and Cherry Streets
Philadelphia PA 19103
Telephone: (215) 988-3338
Facsimile: (215) 988-2757